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VIA ECF

April 21, 2023

The Honorable Reneè Marie Bumb, U.S.D.J.
Chief Judge, United States District Court
Mitchell H. Cohen Building & U.S. Courthouse
4th & Cooper Streets
Camden, NJ 08101

Re: *Corcept Therapeutics, Inc. v. Teva Pharm. USA, Inc.*, No. 18-3632 (consolidated)
Corcept Therapeutics, Inc. v. Teva Pharm. USA, Inc., No. 23-1505

Dear Chief Judge Bumb:

This firm, together with Quinn Emanuel, represents plaintiff Corcept Therapeutics, Inc. ("Corcept") in the above-captioned matters. We write in response to Defendant Teva Pharmaceuticals USA, Inc.'s ("Teva's") April 17, 2023 letter ("Lt. at __") and proposed stipulation (ECF No. 235[1]).

As an initial matter, Corcept agrees with Teva that the two patents in the 23-1505 action are closely related to the patents in the 18-3632 action and that there is no need to try the ***validity*** issues in the 23-1505 action. However, as explained below, the ***infringement*** issues in the 23-1505 action, while related, are materially different from the issues in the 18-3632 action. It seems, however, that the parties agree that adjudication of all such issues can be accomplished on an expedited schedule, with trial occurring as soon as December 2023.

Teva argues that "the dispositive issues in the two cases are materially identical" and that "collateral estoppel" would apply in the 23-1505 action. Neither assertion is correct as it pertains to infringement. With respect to the drug-drug interaction patents (U.S. Patent No. 10,195,214 ("the '214 patent") and U.S. Patent No. 10,842,800 ("the '800 patent")), Teva argues that collateral estoppel applies because the "crux of the infringement dispute on both patents is whether the label for Teva's mifepristone product instructs physicians to administer a strong CYP3A inhibitor to a patient already taking mifepristone"[2] such that the issues are "exactly the

[1] All docket citations are directed to Civil Action No. 18-3632.

[2] The mifepristone products at issue in this litigation are indicated for the treatment of certain patients with Cushing's Syndrome, a rare endocrine disorder, and are unrelated to, and

same in both cases." (Lt. at 2). But Teva overlooks certain claims of the '800 patent, such as independent claim 6, which relates to administering mifepristone to a patient who is ***already*** taking a strong CYP3A inhibitor (not the other way around). The steps of that claimed method in the '800 patent do not require the physician who prescribes the mifepristone to administer a strong CYP3A inhibitor, so the infringement inquiry (as Teva has described it) is necessarily different. And, with respect to both the drug-drug interaction patents (the '214 patent and the '800 patent) and the food-effect patents (U.S. Patent No. 10,500,216 ("the '216 patent") and U.S. Patent No. 10,842,801 ("the '801 patent")), Teva admits that the claimed dosing regimens are different. (Lt. at 2). These differences in the claims will lead to differences in the relevant evidence and in the infringement analyses, and thus preclude the application of collateral estoppel. *Ohio Willow Wood Co. v. Alps S., LLC*, 735 F.3d 1333, 1342 (Fed. Cir. 2013) (holding the doctrine of issue preclusion applies only to unadjudicated patent claims where "the differences between the unadjudicated patent claims and adjudicated patent claims do not materially alter" the inquiry before the court). Accordingly, Teva's proposed stipulation is inappropriate as it pertains to infringement.

With respect to the validity of the drug-drug interaction patents, Teva is estopped from bringing any new validity challenges. Teva sought to invalidate the claims of the '214 patent by filing a Petition for Post-Grant Review before the Patent Trial and Appeal Board ("PTAB"). Following institution, the PTAB found no challenged claims unpatentable, and the Federal Circuit affirmed. *Teva Pharms. USA, Inc. v. Corcept Therapeutics, Inc.*, 18 F.4th 1377 (Fed. Cir. 2021). Thus, by statute, Teva cannot further contest the validity of the '214 patent here. *See* 35 U.S.C. § 325(e). Moreover, due to the relatedness of the '214 patent and '800 patent and the breadth of the PTAB and Federal Circuit decisions, the doctrine of issue preclusion prevents Teva from relitigating certain issues dispositive of any validity challenge against the '800 patent, such as whether "a skilled artisan would have had a reasonable expectation of success for safe co-administration of more than 300 mg of mifepristone with a strong CYP3A inhibitor." *See Teva*, 18 F.4th at 1380. The Federal Circuit has held that a party is precluded from relitigating validity of related patent claims based on a prior determination that was dispositive and applicable to all claims. *Allergan, Inc. v. Sandoz, Inc*., 681 F. App'x 955, 961 (Fed. Cir. 2017). With respect to the food-effect patents, Teva admits that its "invalidity arguments on the [food-effect] patents are exactly the same." Thus, a stipulation regarding validity on the food-effect patents would be appropriate.

Teva also accuses Corcept of delay in bringing the 23-1505 action and of prejudicing Teva. Again, neither accusation is correct. This is not a typical Hatch-Waxman case where a 30-month stay prevents generic launch. As Teva admits, "the 30-month stay has long since expired [and] Teva's ANDA product received final FDA approval." (Lt. at 1). Teva could have launched its generic product at any time since August of 2020. It has simply chosen not to—and

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unaffected by, other litigations regarding the use of mifepristone to terminate pregnancies. Corcept's Korlym® product (and Teva's generic product), both contain black-box warnings that explicitly forbid doctors from prescribing the drug to pregnant patients.

that decision, of Teva's own making, is unaffected by the 23-1505 action. Moreover, to the extent that Teva wanted to resolve any issues related to the '800 and '801 patents, of which it was well aware, at any time over the last two and a half years, Teva could have filed a declaratory judgment action against those patents. Again, Teva chose not to do so. Thus, Teva's claims of prejudice ring hollow.

Moreover, Corcept's decision to file suit on the two additional patents was not a "tactical delay," as Teva alleges. Once Teva lost its Post-Grant Review challenge to the '214 patent, and after the close of expert discovery on April 9, 2021, Corcept moved for summary judgment of infringement on the '214 patent in the first filed action. *See* ECF Nos. 197-198. A finding of infringement on the latest-expiring patent would have obviated the need for further proceedings and would have resolved this matter entirely while conserving party and judicial resources. The Court resolved the motion for summary judgment on February 27, 2023. *See* ECF No. 229. After consulting with Teva, Corcept asserted its additional patents less than three weeks later. Corcept did not assert those patents while the motion for summary judgment was pending because Corcept was confident in the merits of its motion. Corcept is also a small company—with just one commercial product—that did not want to unnecessarily devote resources to litigating a separate action while a case dispositive motion was pending. And Corcept did not attempt to fold its additional patents into the first-filed case immediately upon their issuance in late-November 2020 because, by then: (1) fact discovery had closed, (2) opening expert reports had been submitted, (3) the validity of the '214 patent had been upheld by the PTAB, and (4) Corcept had already developed the record to support its case-dispositive motion. In short, had Corcept's summary judgment motion been granted, it would have mooted the need to assert the additional patents against Teva because Teva would have been enjoined from marketing its ANDA product until after the expiration of Corcept's patents. Thus, Corcept believed the most efficient path forward was to finish expert discovery in the first case and to move for summary judgment. Notably, Teva's actions (and inaction) indicate that ***it agreed with this approach***. Teva filed its own cross-motion for summary judgment on the '214 patent, *see* ECF No. 203, and decided not to file a declaratory judgment action against the additional patents. Teva cannot now complain about "delay" in adjudicating those patents.

Thank you for Your Honor's kind attention to this matter.

Respectfully yours,

William C. Baton

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cc: All counsel of record (via e-mail)